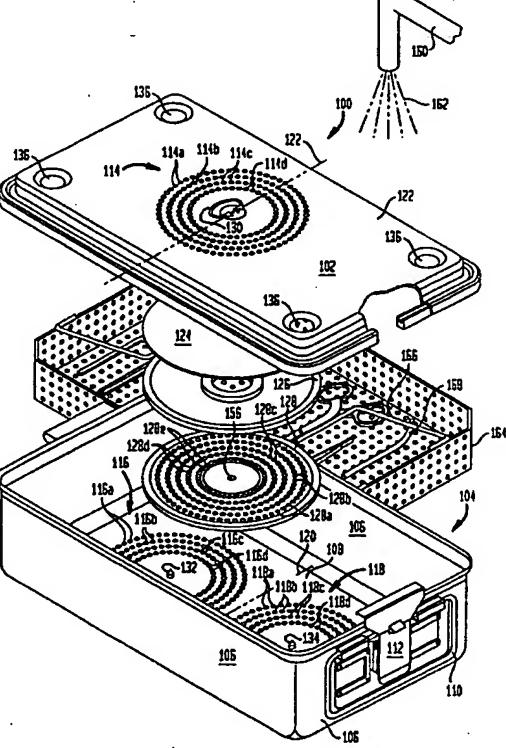




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(54) Title: FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION					
(57) Abstract					
<p>A flash sterilization container (10) comprises a pan (12) forming the bottom of the container holding a tray (14), with a cover (16) forming the top of the container, and a filter element (20). The filter (20) covers an opening in the cover (16) so that the inside of the container (10) formed when the cover is removably sealed to the pan (12) can communicate with the atmosphere surrounding the sealed container allowing steam to enter and exit the container passing through the filter (20). Items to be sterilized are placed on the tray (14) and the cover (16) is attached and sealed to the pan (12). The sealed container is then placed in an autoclave or other source of pressurized steam. The filter is composed of a material which will allow the pressurized steam to pass through but which is relatively impervious to dust and microorganisms thereby maintaining the sterility of the interior of the container and its contents.</p>					
					

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**TITLE: FILTERED GAS PLASMA STERILIZATION  
CONTAINER WITH IMPROVED CIRCULATION**

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**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation-in-part of our co-pending U.S. application serial no. 09/023,055 filed on February 12, 1998, the entire contents and substance of which is hereby incorporated by reference.

**BACKGROUND OF THE INVENTION**

10 1. **Field of the Invention**

The invention relates, in general, to a method for sterilizing medical instruments with steam and, in particular, to a sterilization container useful for flash sterilization and gas plasma sterilization, which includes a filter that permits maximum steam or gas sterilant penetration and prevents microorganisms and dust from entering.

15 2. **Description of Related Art**

Steam sterilization is a common method used for the sterilization of items, especially medical instruments by processing the items in an autoclave and exposing them to high-pressure steam. This method requires the wrapping of individual items, heating the items with steam and then waiting for a drying/cooling period. Often during 20 surgical procedures commonly used instruments need to be quickly sterilized after use or inadvertent contamination. Under such circumstances the standard autoclave method would take too long. An alternative sterilization method, which can be used under these circumstances, is known as flash sterilization. In flash sterilization metal instruments are not wrapped but are heated directly by the steam allowing sterilization 25 in a reduced period of time. One drawback to the use of flash sterilization is the lack of a drying period. When the items are still moist and hot from sterilization,

microorganisms and dust can contaminate the items when they are transported from the autoclave/sterilizer. Nevertheless, flash sterilization results in reduced exposure time.

One common design for containers for flash sterilization is described in U.S. Patents 5,097,865 and 4,748,003. Such containers use valves which require greater than atmospheric pressures to open the valves and allow the high-pressure steam to enter the container but are closed under normal pressure conditions. This approach has a number of disadvantages. Such containers must be opened to allow the steam to escape, thus breaking the sterile field. Even if kept sealed, these containers cannot maintain the sterile field for longer than 24 hours. Also, the high temperature, high-pressure valves needed for this method are very complex and very expensive. In addition, such containers do not provide an indication as to whether or not the valve properly functioned to allow the high pressure steam to enter the container.

The present invention facilitates the use of flash sterilization while retaining the advantage of standard autoclave sterilization by maintaining the sterility of the items in the sterilization container. Instead of a costly, complicated valve system the present invention uses a passive filter system which is capable of allowing steam to enter and exit the container and still keep microorganisms and dust out, maintaining the sterile field in the container for long term storage. The present invention, especially in the mid-size container, provides the additional advantage of reducing the time required for steam sterilization.

In addition to flash steam sterilization the industry is beginning to use gas plasma as an alternative. One commercially available gas plasma system is sold as STERRAD® by Advanced Sterilization Products, a division of the Johnson & Johnson Company. Gas plasma has known advantages over steam sterilization, including

sterilizing at a lower temperature than required for steam sterilization, which is beneficial when sterilizing temperature-sensitive devices. However, it has been learned that frequently the sterilizing gas plasma does not reach all important surfaces on the inside of the sterilization container, especially where long tubular instruments or cables 5 are contained. Accordingly, there are believed to be very few, if any, sterilization containers approved for use with gas plasma, especially in the mid-size range. Clearly a technique is missing in the prior art to guarantee satisfactory circulation of gas plasma within a sterilization container, especially where it is critical to reach the edges and corners of the interior of the sterilization container and to penetrate internal components 10 such as laparoscopic guides and tubing. The present invention, however, maintains its efficacy when utilized with gas plasma as the sterilant.

#### SUMMARY OF THE INVENTION

Briefly described, the invention comprises a sterilization container and a flash 15 sterilization method for sterilizing items, which allow for extended, sterile storage of the sterilized items. The flash sterilization method uses a sterilization container having a pan, a cover and one or more filters for preventing dust and microorganisms from entering the container and contaminating the sterilized items while still allowing steam or gas plasma in and out of the container during the sterilization process. These 20 containers can be used in the flash sterilization process commonly used in surgical theaters. The filter can be permanently mounted in the container or can be removable for replacement with new or different types of filters. Removable filters will allow for the retrofitting of currently used containers with the filters so that new containers do not need to be purchased to take advantage of the filtered flash sterilization method of the

present invention. The filter can be removably attached to the container, manufactured as an integral part of the container, or incorporated into a self-contained removable filter unit.

Another aspect of the present invention comprises a novel filter retainer used for 5 attaching a filter to the sterilization container. The filter retainer has a plurality of steam penetration holes which can be of various sizes and shapes allowing sufficient steam to enter the container. The filter retainer also comprises one or more gaskets for maintaining a seal between the filter retainer and the sterilization container as well as a locking means for removably attaching the retainer to the container.

10 Another alternative embodiment of the invention provides for a single set of vent holes in the center of the lid, or cover, of the container and two sets of vent holes, arranged in a circular fashion, located in the base of the pan or bottom of the container. The second and third sets of vent holes in the base are located on opposite sides of the minor axis center line of the base in such a way that they do not overlap. Gas plasma 15 passing through the first set of vent holes in the lid is then forced to travel to the extremes of the container in order to be exhausted thereby guaranteeing that all parts of the tray or sterilizable instruments on the inside come into contact with the gas plasma as well as the edges and corners and interior of the container.

According to yet another embodiment of the invention, a pair of vent means, 20 comprising a first and fourth set, are located in the lid in a manner similar to the way the second and third set of vent holes are located in the base. This also helps to guarantee thorough circulation of the gas plasma within the container. These two improvements are especially suited for use with mid-size sterilizable containers that employ gas plasma as the sterilizing agent. This invention, however, enhances the

efficacy of all methods of sterilization, including steam sterilization and gas plasma sterilization. The first, second, third and fourth sets of vent holes are preferably each arranged in four concentric circles having the holes on their circumference. Other alternative, symmetrical patterns, like square, would also be acceptable. The keeper 5 plate on the bottom of the container preferably includes a similar set of holes, but offset so that there can be no "strikethrough" of sharp objects through the filter underneath the series of vent holes but above the keeper plate.

These and other features of the invention may be more fully understood by reference to the following drawings.

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#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1A is a perspective view of the preferred embodiment of the flash sterilization container invention.

Fig. 1B is a top perspective view of the flash sterilization container cover with a 15 filter retainer.

Fig. 1C is a perspective view of the flash sterilization container invention with the top surface of the lid having a D-ring attached to it.

Fig. 2A is an exploded perspective view of the flash sterilization container filter invention.

20 Fig. 2B is a partial view of a cover opening configuration.

Fig. 3A is a side elevational view of the filter retainer invention.

Fig. 3B is a top plan view of the filter retainer invention with the locking means in the locked position.

Fig. 3C is a top plan view of the filter retainer invention with the locking means in the unlocked position.

Fig. 4A is a partial, side elevational view of a flash sterilization container cover with an incorporated filter.

5 Fig. 4B is a partial, side elevational view of a flash sterilization container and a filter cartridge.

Fig. 5A is an exploded view of an alternative embodiment of the invention especially suitable for use with gas plasma in which the base of the container includes two sets of circular vent holes located on opposite sides of the center line of the minor 10 axis of the container.

Fig. 5B is a top plan view of the lid of the alternative embodiment illustrated in Fig. 5A.

Fig. 5C is an elevational cross-sectional view of the lid illustrated in Fig. 5B.

Fig. 5D is a partial, cross-sectional exploded view of the top, or first set, of 15 circular vent means illustrated in a manner in which the pull ring is attached to the lid.

Fig. 5E is a detailed, cross-sectional end view of the lid of Fig. 5B illustrated in a manner in which the snap-on post attaches to the filter retainer plate.

Fig. 5F illustrates the bottom, or pan, of the gas plasma alternative embodiment illustrating how the second and third set of circular vent means are located on opposite 20 sides of the center line of the minor axis of the bottom portion.

Fig. 6A is an exploded view of another alternative embodiment of the gas plasma container illustrating a fourth set of circular vent means located adjacent to said first set of circular vent means in the top of lid of the container.

Fig. 6B is a top plan view of the lid of the alternative embodiment illustrated in Fig. 6A.

Fig. 6C is a side elevational cross-sectional view of the lid illustrated in Fig. 6B.

Fig. 6D is a partial, detail exploded view of the first set of circular vent means illustrating the manner in which the pull ring is attached to the lid.

#### DETAILED DESCRIPTION OF THE INVENTION

During the course of this description like numbers will be used to identify like elements according to the different figures that illustrate the invention.

The flash sterilization container invention 10 according to a preferred embodiment thereof is illustrated in Fig. 1. A sterilization container 10 comprises a pan 12, which forms the bottom of the container that holds and supports a conventional sterilizable tray 14, and a cover 16, which forms the top of the container. The cover is removably attached to the pan to form a hermetically sealed container. This can be accomplished by conventional means such as hinges and clamps and a sealing gasket.

The cover 16 is provided with an opening 18 at its top. This opening 18 is covered with a filter 20 to allow steam to enter and exit the container through the opening by passing through the filter. The filter can be removably or permanently attached to the cover. This filter is made of a material, or combination of materials, such that the filter is permeable to the flow of steam but will inhibit dust or other airborne particles or microorganisms from passing through. Examples of such materials include paper, TEFLON<sup>®</sup>, a registered trademark of E.I. Du Pont de Nemours and Co., Inc., porous stainless steel, polysulfone, and hydrophobic material, such as GORETEX<sup>®</sup>, a registered trademark of W.L. Gore & Associates, and Kimguard<sup>®</sup>, a trademark of the Kimberly-Clark Corporation. The filter is attached to the cover by means which will prevent any

steam, dust or other airborne particles or microorganisms from passing through the opening in the cover without passing through the filter.

In the preferred embodiment, the filter 20 is placed over the opening 18 in the top of the cover 16 and the filter is attached to the cover by a filter retainer 30. The 5 preferred embodiment of such a filter retainer is illustrated in figures 1A, 1B, 2A, 3A and 3B. The filter retainer 30 comprises a filter retainer disc 32 and a means for sealing the filter retainer disc to the cover. The filter retainer disc has an inner disc 34, a middle ring 36, and an outer ring 38. The middle ring 36 has a plurality of holes 40 to allow the flow of steam through the filter retainer disc 32, through the filter 20, and 10 through the opening 18 in the cover 16. The filter retainer can have one or more sealing means for forming a seal between the filter and the cover. The outer ring 38 has a means for forming a seal between the filter and the cover. In one embodiment the outer ring has an inverted-u shaped cross-section. A gasket 46 is placed in the inverted-U outer ring and can be made of silicone, neoprene, TEFLON®, a registered trademark 15 of E.I. Du Pond de Nemours and Co., Inc., or any other suitable material. Inner disc 34 may also have a sealing means if necessary, such as a gasket 48.

The preferred embodiment of a means for attaching the filter retainer to the cover is illustrated in figures 1A, 1B, 2A, 3A, and 3B. Pin 50 extends upwards from the top surface of the cover 16. Inner disc 34 of the filter retainer disc 32 has a hole 42 20 for accepting pin 50. Pin 50 has sufficient length to extend past the top surface of the filter retainer 30 when the filter retainer is placed on the cover 16 allowing the hole in the inner disc 42 to engage the pin 50. Pin 50 is preferably located in the center of the opening 18 in the cover 16. To locate the pin in the proper position, the opening in the cover can be, for example, a circular opening with cross pieces such as those illustrated

in figure 2A. In an alternate embodiment, the opening in the cover can be comprised of a multiplicity of smaller openings in the cover, as depicted in Fig. 2B. A locking means is located on the inner disc which engages the pin 50 and holds the filter retainer in place.

5 The preferred locking means is comprised of a sliding plate 60 which is movably attached to the inner disc 34 of the filter retainer disc 32 with a hinge pin 62 extending from the inner disc 34 of the filter retainer disc 32, so that the sliding plate 60 rotates about the center of the hinge pin 62 while remaining in contact with the inner disc. The sliding plate 60 has an arc-shaped pin slot 64 having an effective radius equal  
10 to the distance from the hinge pin 62 to the hole in the center of the inner disc 42, whereby the center of the hole in the inner disc maintains alignment with the center of the arc-shaped slot throughout the rotation of the sliding plate.

The retainer pin 50 is comprised of a cylindrical body 52 having opposite ends and an outside diameter essentially equal to the inside diameter of the hole 42 in the  
15 filter retainer disc, a cylindrical neck 54 having a diameter smaller than the diameter of the body and equal to the width of the arc shaped slot 64, and a cylindrical head 56 having a top and a bottom and having a diameter larger than the pin neck 54, preferably equal to the diameter of the pin body 52. One end of the pin body 52 is attached to the cover 16 by conventional means, such as, a rivet 58, a screw, a thread, or a spot weld.  
20 Pin neck 54 is attached to the end of the pin body 52 opposite the attachment to the cover. The bottom of the pin head is attached to the pin neck at the end opposite the pin neck's attachment to the pin body. The retainer pin can be made of separate elements attached by conventional means or preferably manufactured from a single piece of stock. The length of the pin body is essentially equal to the distance from the

top surface of the cover to the top surface of the inner disc. The length of the pin neck is at least equal to the thickness of the sliding plate. The combined length of the pin body and pin neck is such that the bottom of the pin head is slightly lower than the top surface of the sliding plate 60 so that when the arc-shaped pin slot 64 engages the pin neck 54, the filter retainer disc 32 will be forced toward the cover, compressing the gaskets 46, 48, and creating a seal between the filter retainer 30 and the cover 16. The top of the pin head 56 can have a taper to facilitate the insertion of the retainer pin 50 through the hole in the filter retainer disc 42 and arc-shaped slot in the sliding plate 64.

The arc shaped slot 64 has a width essentially equal to the outside diameter of the pin neck and a length at least twice as long as the outside diameter of the pin head. 10 At one end of the arc-shaped slot 64, the width of the slot is increased to allow the pin head to pass through the arc-shaped slot.

A filter is attached to the cover with the filter retainer by placing a filter 20 over the hole 18 in the cover 16, the sliding plate 60 is positioned so that the end of the arc-shaped slot 64 having an increased width is aligned with the hole in the inner disc 42, the filter retainer 30 is then placed over the opening in the cover 16 so that the retainer pin 50 passes through the hole in the inner disc 42 and the enlarged end of the arc-shaped slot 64, and the sliding plate 60 is then rotated so that the arc-shaped slot 64 engages the pin neck 54, thereby preventing the pin from passing back through the arc-shaped slot and thus attaching the filter retainer to the cover. 15 20

In a preferred embodiment, the filter retainer 30 has a means for limiting the rotation of the sliding plate 60 and facilitating the positioning of the sliding plate in an "open" position, where the enlarged end of the arc-shaped slot 64 lines up with the hole in the inner disc 42, and a "locked" position, where the opposite end of the arc-shaped

slot lines up with the hole in the inner disc. One embodiment of a limiting means incorporates an arc-shaped limiting slot 66 on the sliding plate 60. The arc of the limiting slot 66 is parallel to the arc of the arc-shaped slot 64 and has an effective radius larger than the radius of the arc-shaped slot 64. A locating pin 68 is attached to, 5 and extends from, the inner disc 34 such that it engages one end of the limiting slot 66 when the sliding plate 60 is in the locked position and engages the opposite end of the arc-shaped slot when the sliding plate is in the unlocked position. The locating pin 68 is preferably hemispherical-shaped to facilitate the movement of the sliding plate 60 over the locating pin 68. A hemispherical locating pin 68 can be made, for example, by 10 inserting and attaching a ball bearing in a hole in the inner disc 34. The width of the limiting slot 66 is slightly less than the diameter of the locating pin 68. The width of the limiting slot 66 at each of the two, opposite ends, is enlarged slightly, forming two holes each having a diameter slightly larger than the diameter of the locating pin 68. Consequently, the sliding plate 60 is held in the locked and open positions when the 15 locating pin 68 engages each of the holes in the ends of the limiting slot 66, requiring the application of an external force to move the sliding plate between the two positions.

The sliding plate 60 preferably has a handle 70 to facilitate moving the plate between the open and closed positions. The handle 70 preferably extends parallel to the plane of the sliding plate. The handle 70 can be attached to the sliding plate or 20 manufactured with the sliding plate as a single piece.

As described above, the preferred embodiment comprises a sterilization container having a filter retainer mechanism. Alternative embodiments comprise having the filter manufactured as an integral part of the container as depicted in Fig.

4A, or having the filter incorporated into a self-contained removable filter unit or cartridge as depicted in Fig. 4B.

A further alternative embodiment comprises a D-ring attached to the end of pin 50 connected to the cover 16. In this embodiment, the filter and filter retainer are 5 mounted on the inside of the sterilization container. This arrangement permits the external D-ring to be used as a handle to lift the cover without coming into contact with the side edges of the cover 16, thereby reducing the risk of contamination of the container contents.

While the foregoing embodiment works sufficiently well in a flash sterilization 10 environment, it has been found that improvements to the basic structure of the invention are desirable if used with gas plasma. Gas plasma as a sterilization medium is fairly new and is available from, among others, Advanced Sterilization Products, a division of Johnson & Johnson, under the trademark STERRAD®. Gas plasma has certain advantages over the prior art. For example, ethylene oxide has been banned 15 thereby making it more difficult to find suitable alternatives. In addition, steam sterilization cannot be used with a number of modern tools, such as cannulas, lumens, scopes, fiber optic cables, and cameras, without damaging them. While gas plasma clearly has certain distinct advantages, it has been found that it does not operate 20 suitably well with all types of containers that were suitable for use with steam sterilization. Part of the problem is that the gas plasma does not circulate as aggressively as steam inside the container, and does not reach areas such as the corners. thereby leaving the potential for unsterilized surgical instruments or the like. Steam sterilization avoids the absorption problem by having a super-saturated environment of water molecules. The present invention, however, has provided a way for making gas

plasma acceptable for use in sterilization containers, especially those in the mid-size range. For the purposes of this disclosure, mid-size is defined as approximately 15 – 18" in length, 9 – 12" in width and 2 – 10" in depth. The present invention, especially in the mid-size container, has several advantages, including but not limited to, the 5 following: 1) it cuts the exposure time in steam sterilization; 2) it improves the effectiveness of gas plasma sterilization; and 3) it is more efficacious for gravity displacement applications.

A first alternative embodiment 100 of the improved gas plasma sterilization container apparatus is illustrated in the exploded view of Fig. 5A. The container 100 10 includes a top or lid 102 that sits on top of a bottom or pan 104. Bottom 104 includes four sidewalls 106 and a bottom or base 108. A pair of wire handles or bales 110 are located on opposite ends of the bottom portion 104 and are held in place by a pair of lockable latches 112.

A first set of vent holes 114 is located in top 102. The vent holes 114 are 15 preferably arranged as a group of four concentric circles with holes 114a, 114b, 114c and 114d in each, respectively. In all, the total number of holes may range from 100 to 500 and have a size that ranges in diameter from, but not limited to, 3/16" to 5/16". The first set of vent holes 114 is located on the central axis 122 of the short dimension 20 of the lid 102. The first set of vent holes 114 allows the sterilizing medium 162 to pass into the container. A pull ring 130, attached to a base 142 sits in the middle of the first set of vent holes 114 and is connected there by rivet assembly 144a, 144b, and 144c as shown in exploded detail in Fig. 5D. The lid 102 also includes four recessed dimples 136 which are adapted to engage with complimentary dimples or projections in the base

**108** (not shown) so that the containers **100** can be stacked on each other and permit circulation of gas plasma therethrough at the same time.

A second set of vent holes **116** and a third set of vent holes **118** are located in the base **108** on symmetrical opposite sides of center line **120** which represents the 5 minor axis of the base **108**. The second set of vent holes **116** also comprises four concentric circles having holes **116a**, **116b**, **116c** and **116d** of the same dimensions with regard to the first set of vent holes **114**. A hold-down stud **132** is located in the center of the concentric circles and is intended to make a snap fit with the retainer plate for the hydrophobic filter that goes therebetween. Similarly, the third set of vent holes 10 **118** comprises four sets of concentric circles having holes **118a**, **118b**, **118c** and **118d** therein. A central post or stud **134** is also located in the middle thereof and adapted to snap into and engage a hydrophobic filter retainer plate in the manner previously described with regard to the flash sterilization embodiment. Associated with the first set of vent holes **114** is a circular hydrophobic filter disk **124**, a hold down ring **126** and 15 a perforated filter retainer plate **128**. A central hole **156** in the retainer plate **128** snaps into and engages a stud **146** in the container as illustrated in Fig. 5E. A similar set of hydrophobic filters, rings, and retainer plates is associated with the second and third set of vent holes **116** and **118** as illustrated in Fig. 5F. Hydrophobic filters **124** should be utilized when gas plasma acts as the sterilizing medium, whereas cellulosic filters can 20 be used when steam or ethylene oxide acts as the sterilizing medium. The **TYVEK**<sup>®</sup>, a trademark of E.I. du Pont de Nemours & Company, brand of polyethylene/polypropylene spun fiber is acceptable, as is **Kimguard**<sup>®</sup>, a trademark of the Kimberly-Clark Corporation. The alternative embodiments **100** and **200** also work best with hydrophobic filters such as described above. In addition, hydrophobic filters

do not absorb water, which allows for a quicker drying time. The concentric holes 128a, 128b, 128c, 128d and 128e, are preferably offset from the holes 114a, 114b, 114c, and 114d so as to the prevent "strikethrough". That is to prevent sharp objects from entering the holes 114a, 114b, 114c and 114d and exiting through 128a, 128b, 128c, 128d or 128e. As illustrated in Fig. 5C the top or lid 102 includes a groove 138 which retains a gasket 140 which sits on top of the upper lip 150 of the bottom or base pan 104 as shown in Fig. 5F. Fig. 5F also shows in further detail how the bottom perforated retainer plate 152 attaches to the bottom stud 132 and keeps a hydrophobic filter in place above the second set of vent holes 116. Similarly, Fig. 5F also illustrates how another perforated filter retainer plate 154 engages snap on stud 134 to hold another hydrophobic filter in place above the third set of perforated vent holes 118.

The structure just described works especially well with gravity displacement or gas plasma. The gas plasma enters through the vent holes 114, passes through the hydrophobic filter 124 and emerges through the perforated base plate 128. Because the top vent holes 114 are not located directly above the bottom pair of vent holes 116 and 118, the gas plasma is forced to migrate, and become somewhat turbulent as it attempts to find an exit through the second and third set of circular vent holes 116 and 118, respectively. This forces the gas plasma to more thoroughly mix and contact medical instruments or the like inside of the container 100 and also forces it further towards the corners and edges of the container. As a consequence, the invention described is one of a few containers, if any, that has been approved by major manufacturers for use with gas plasma. It is believed that no sealed container in the mid-size range for sterilization of blades and cannulas has been approved at the present time. The present invention in the mid-size range with the offset sets of vent holes works in all methods of

sterilization, including flash sterilization, steam sterilization, and gas plasma sterilization.

A second alternative embodiment 200 of the gas plasma version is illustrated in an exploded view shown in Fig. 6A. The base, or bottom pan 104 of the embodiment 5 200 is identical in all respects to the base 104 illustrated in Fig. 5A and associated with the first gas plasma alternative embodiment 100. Namely, the base 104 also includes a pair of offset circular vent holes 116 and 118 each having a hydrophobic filter and a retainer plate associated therewith as seen, for example, in detail in Fig. 5F. The difference between embodiment 100 and 200 is that alternative embodiment 200 10 includes a pair of circular sets of vent holes 202 and 204 arranged symmetrically on opposite sides of the small dimension center line 226. The structure of the first and second set of vent holes 202 and 204 is identical to the structure of the set of vent holes 114 in the lid 102 of embodiment 100 as illustrated in Figs. 5A – 5F. Namely, the first set of vent holes 202 comprises four concentric circles of vent holes 202a, 202b, 202c 15 and 202d. A pull ring 218 connected to a base 220 is located in the center of the concentric circles 202. Pull ring 218 is attached by a rivet assembly 244a, 244b, and 244c as illustrated in exploded detail in Fig. 6D. Similarly, the second set of vent holes 204 comprises four concentric circles having vent holes 204a, 204b, 204c and 204d arranged around a pull ring 222 attached to a base 224 and connected to the lid 226 in 20 the same manner as illustrated in Fig. 6D. The first set of vent holes 202 has associated with it a hydrophobic filter disk 206, a ring 208, and a perforated retainer plate 210 that snaps and attaches to a post on the bottom side of the base plate 220 in the same manner that the post 146 of the embodiment 100 engages its perforated retainer plate 128 as illustrated in Fig. 5E. Similarly, another hydrophobic filter disk 212 is located

under the second set of vent holes 204, and has an associated ring 214 and perforated retainer plate 216 below it which also engages with a snap on post associated with pull ring 222 and base plate 224. This second alternative embodiment 200 also provides for improved circulation of the gas plasma through the container so as to contact all the 5 surgical instruments and the corners of the device.

In summary, the two gas plasma alternative embodiments 100 and 200 make it possible to convert a flash sterilization container such as illustrated in Figs. 1A through 4B into a version which is imminently acceptable and suitable for use with mid-size sterilization containers. Not only does it work with mid-size containers, it also permits 10 sterilization to take place in approximately half the time and works especially well in a gravity displacement environment. Moreover, delicate instruments, such as cameras which cannot be sterilized with steam or ethylene oxide, can be effectively sterilized.

While the invention has been described with reference to the preferred embodiment, it will be appreciated by those of ordinary skill in the art that 15 modifications can be made to the structure and form of the invention without departing from the spirit and scope thereof.

**WE CLAIM:**

1. A sterilization container apparatus (100, 200) used for sterilizing instruments placed therein and surrounded by a sterilizing medium, said container (100, 200) apparatus comprising:

5 a lid (102, 226) having a first set of vent holes (114, 202) therein;  
a bottom (104) attachable to said lid (102, 226), said bottom (104) having

sidewalls (106) and a base (108); and,

10 at least a second (116) and third (118) set of vent holes located in the base

(108) of said bottom (104),

wherein a sterilizing medium passes through said first set of vent holes (114, 202), around the inside of said container (100, 200) and exits through said second (116) and third (118) set of vent holes.

15 2. The apparatus of claim 1 further including:

a filter medium (124, 206, 212) associated with each of said sets of vent holes (114, 116, 118, 202, 204),

wherein said sterilizing medium passes through said vent holes (114, 116, 118, 202, 204) and said filter medium (124, 206, 212).

20 3. The apparatus of claim 2 wherein said vent holes (114, 116, 118, 202, 204) comprise a plurality of holes arranged in a symmetrical pattern.

4. The apparatus of claim 3 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric patterns.

5. The apparatus of claim 4 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric circles.

6. The apparatus of claim 5 wherein said base (108) of said bottom (104) has a minor axis center line (120), and

5 wherein said second (116) and third (118) set of vent holes are located

on

opposite sides of said center line (120) and are offset from the first set of vent holes (114, 202) in the lid (102, 226).

7. The apparatus of claim 6 wherein said filter medium (124, 206, 212) 10 comprises a hydrophobic filter material.

8. The apparatus of claim 7 further comprising:

a fourth set of vent holes (204) located in said lid (226), and,

15 wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

9. The apparatus of claim 8 wherein said sterilization medium (162) consists of steam or gas plasma.

10. The apparatus of claim 9 wherein said filter medium (124, 206, 212) comprises a hydrophobic filter material when utilizing gas plasma as the sterilizing 20 medium (162).

11. The apparatus of claim 9 wherein said filter medium (124, 206, 212) comprises a cellulosic filter material when utilizing steam or ethylene oxide as the sterilizing medium (162).

12. A system for sterilizing sterilizable items in a container with a gas plasma, said system comprising:

means for introducing a gas plasma (160, 162);

5 a lid (102, 226) having a first set of vent holes (114, 202) located therein;

a bottom (104) attachable to said lid (102, 226) said bottom (104) further including a base (108) having a center line (120) through its minor planar dimension;

10 at least a second (116) and third (118) set of vent holes located on opposite sides of said minor dimension center line (120) of said base (108); and,

15 filter means (124, 206) located adjacent to said sets (114, 202, 116, 118) of vent holes,

wherein said gas plasma passes through said first set (114, 202) of vent holes, comes into contact with said sterilizable items, and exits through said second (116) and third (118) sets of vent holes.

16 13. The apparatus of claim 12 further including:

a filter medium (124, 206, 212) associated with each of said sets of vent holes (114, 116, 118, 202, 204),

wherein said sterilizing medium passes through said vent holes (114, 116, 118, 202, 204) and said filter medium (124, 206, 212).

20 14. The apparatus of claim 13 wherein said vent holes (114, 116, 118, 202, 204) comprise a plurality of holes arranged in a symmetrical pattern.

15. The apparatus of claim 14 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric patterns.

16. The apparatus of claim 15 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric circles.
17. The apparatus of claim 16 wherein said base (108) of said bottom (104) has a minor axis center line (120),
- 5 wherein said second (116) and third (118) set of vent holes are located on opposite sides of said center line (120).
18. The apparatus of claim 17 wherein said filter medium (124, 206, 212) comprises a hydrophobic filter material.
19. The apparatus of claim 18 further comprising:
  - 10 a fourth set of vent holes (204) located in said lid (226), and, wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

**AMENDED CLAIMS**

[received by the International Bureau on 25 March 1999 (25.03.99);  
new claims 20-30 added; remaining claims unchanged (5 pages)]

1. A sterilization container apparatus (100, 200) used for sterilizing instruments placed therein and surrounded by a sterilizing medium, said container (100, 200) apparatus comprising:

a lid (102, 226) having a first set of vent holes (114, 202) therein;

a bottom (104) attachable to said lid (102, 226), said bottom (104) having sidewalls (106) and a base (108); and,

at least a second (116) and third (118) set of vent holes located in the base (108) of said bottom (104),

wherein a sterilizing medium passes through said first set of vent holes (114, 202), around the inside of said container (100, 200) and exits through said second (116) and third (118) set of vent holes.

2. The apparatus of claim 1 further including:

a filter medium (124, 206, 212) associated with each of said sets of vent holes (114, 116, 118, 202, 204),

wherein said sterilizing medium passes through said vent holes (114, 116, 118, 202, 204) and said filter medium (124, 206, 212).

3. The apparatus of claim 2 wherein said vent holes (114, 116, 118, 202, 204) comprise a plurality of holes arranged in a symmetrical pattern.

4. The apparatus of claim 3 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric patterns.

5. The apparatus of claim 4 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric circles.

*AMENDED SHEET (ARTICLE 19)*

6. The apparatus of claim 5 wherein said base (108) of said bottom (104) has a minor axis center line (120), and

wherein said second (116) and third (118) set of vent holes are located on opposite sides of said center line (120) and are offset from the first set of vent holes (114, 202) in the lid (102, 226).

7. The apparatus of claim 6 wherein said filter medium (124, 206, 212) comprises a hydrophobic filter material.

8. The apparatus of claim 7 further comprising:

a fourth set of vent holes (204) located in said lid (226), and,

wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

9. The apparatus of claim 8 wherein said sterilization medium (162) consists of steam or gas plasma.

10. The apparatus of claim 9 wherein said filter medium (124, 206, 212) comprises a hydrophobic filter material when utilizing gas plasma as the sterilizing medium (162).

11. The apparatus of claim 9 wherein said filter medium (124, 206, 212) comprises a cellulosic filter material when utilizing steam or ethylene oxide as the sterilizing medium (162).

12. A system for sterilizing sterilizable items in a container with a gas plasma, said system comprising:

means for introducing a gas plasma (160, 162);

a lid (102, 226) having a first set of vent holes (114, 202) located therein;

a bottom (104) attachable to said lid (102, 226) said bottom (104) further including a base (108) having a center line (120) through its minor planar dimension;

at least a second (116) and third (118) set of vent holes located on opposite sides of said minor dimension center line (120) of said base (108); and,

filter means (124, 206) located adjacent to said sets (114, 202, 116, 118) of vent holes,

wherein said gas plasma passes through said first set (114, 202) of vent holes, comes into contact with said sterilizable items, and exits through said second (116) and third (118) sets of vent holes.

13. The apparatus of claim 12 further including:

a filter medium (124, 206, 212) associated with each of said sets of vent holes (114, 116, 118, 202, 204),

wherein said sterilizing medium passes through said vent holes (114, 116, 118, 202, 204) and said filter medium (124, 206, 212).

14. The apparatus of claim 13 wherein said vent holes (114, 116, 118, 202, 204) comprise a plurality of holes arranged in a symmetrical pattern.

15. The apparatus of claim 14 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric patterns.

16. The apparatus of claim 15 wherein said vent holes (114, 116, 118, 202, 204) are arranged in a plurality of concentric circles.

17. The apparatus of claim 16 wherein said base (108) of said bottom (104) has a minor axis center line (120),

wherein said second (116) and third (118) set of vent holes are located on opposite sides of said center line (120).

18. The apparatus of claim 17 wherein said filter medium (124, 206, 212) comprises a hydrophobic filter material.

19. The apparatus of claim 18 further comprising:

a fourth set of vent holes (204) located in said lid (226), and,

wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

20. The apparatus of claim 19 wherein said gas plasma has an electric field effect.

21. The apparatus of claim 20 wherein said system is comprised of materials which enable said electric field effect of the gas plasma to form a secondary electric field within said container.

22. A method for sterilizing items comprising the steps of

a) placing the items to be sterilized in a container apparatus, said container apparatus comprising

a lid (102, 226) having a first set of vent holes (114, 202) therein;

a bottom (104) attachable to said lid (102, 226), said bottom (104) having sidewalls (106) and a base (108); and,

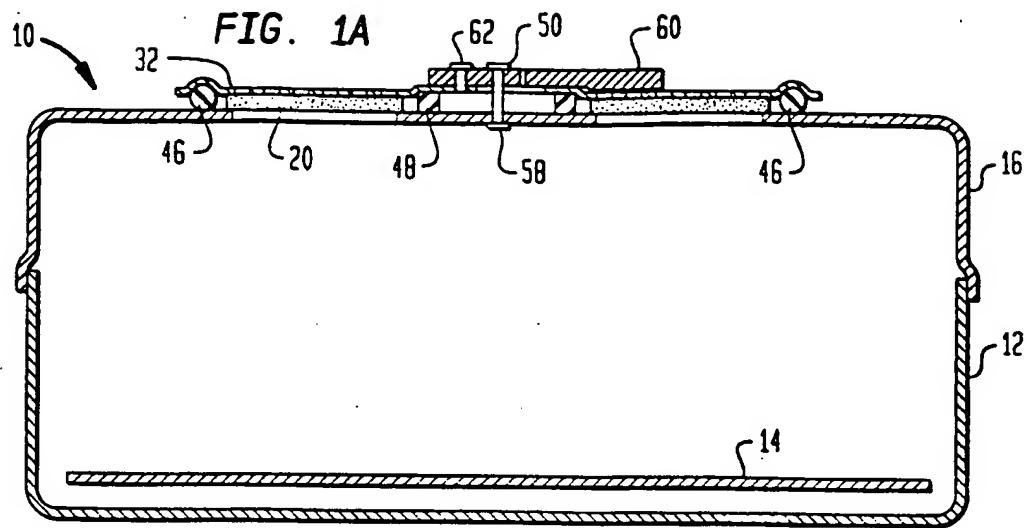
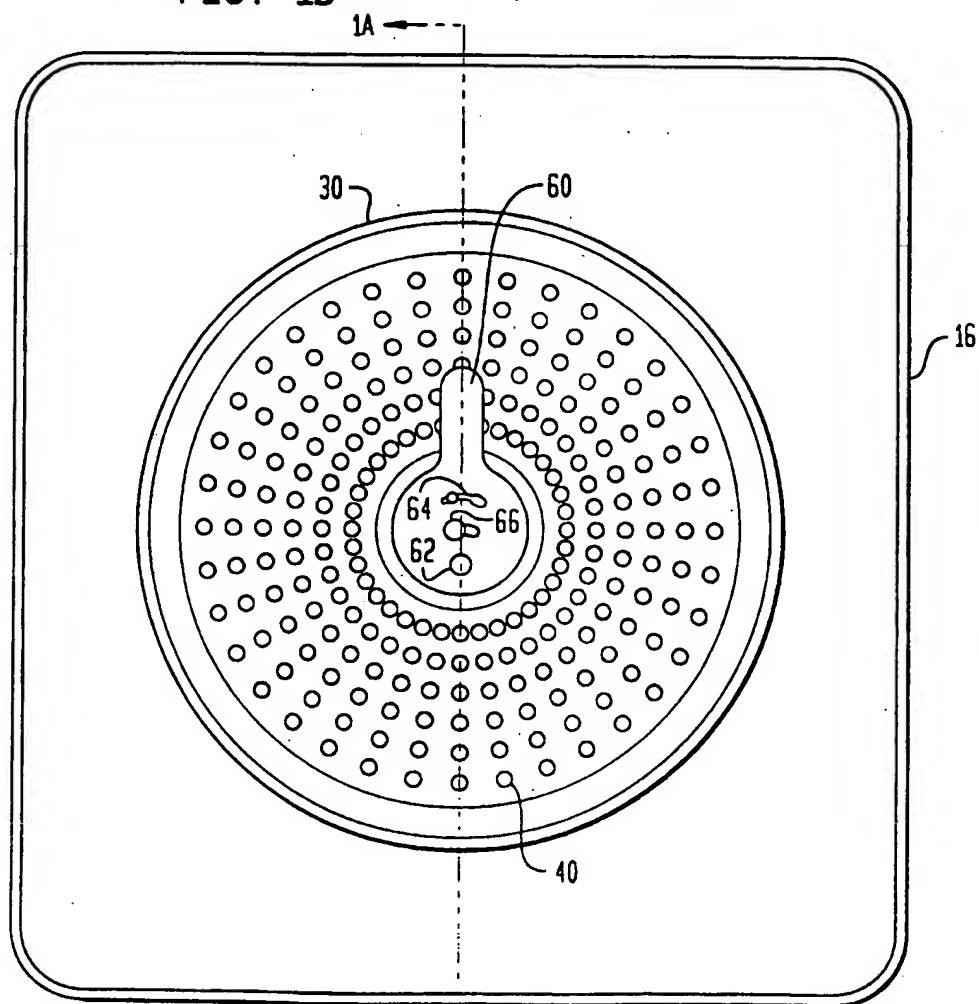
two or more sets of vent holes (116, 118) located in the base (108) of said bottom (104),

b) passing a sterilizing medium through said first set of vent holes (114, 202), around the inside of said container (100, 200) and out of said container through said two or more sets of vent holes (116, 118).

23. The method of claim 22 wherein said container apparatus further comprises:  
a filter medium (124, 206, 212) associated with each of said sets of vent holes (114, 116, 118, 202, 204),  
wherein in step b) said sterilizing medium passes through said vent holes (114, 116, 118, 202, 204) and said filter medium (124, 206, 212).

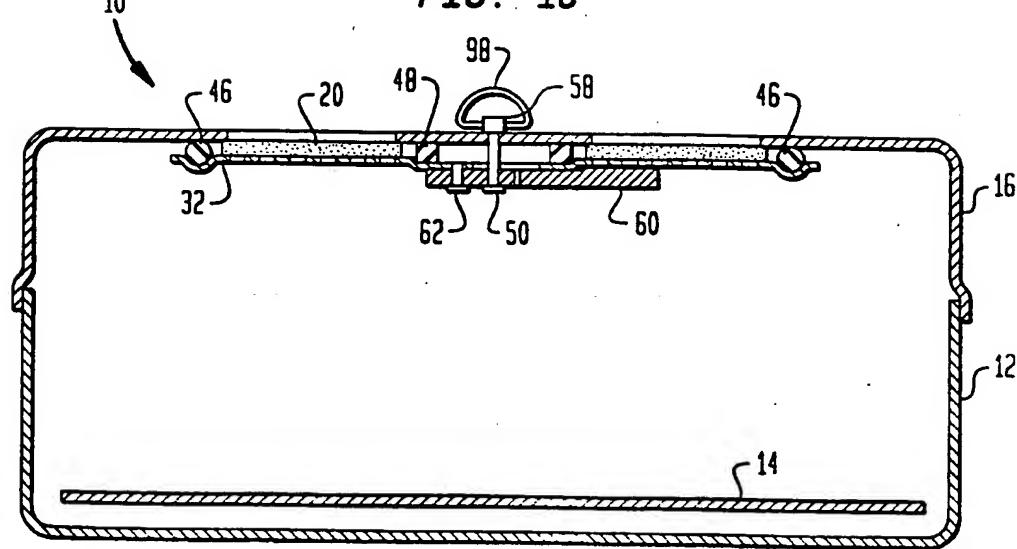
24. The method of claim 23 wherein said sterilization medium is a gas plasma.  
25. The method of claim 24 wherein said gas plasma having an electric field effect.  
26. The system of claim 25 wherein said gas plasma electric field effect generates a secondary field effect within said container apparatus.  
27. The method of claim 26 wherein said container apparatus is comprised of materials which enable said electric field effect of the gas plasma to form said secondary electric field within said container apparatus.  
28. The method of claim 27 wherein said container is composed of a metal.  
29. The method of claim 28 wherein said metal is electrically conductive.  
30. The method of claim 28 wherein said metal is aluminum.

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**FIG. 1B**

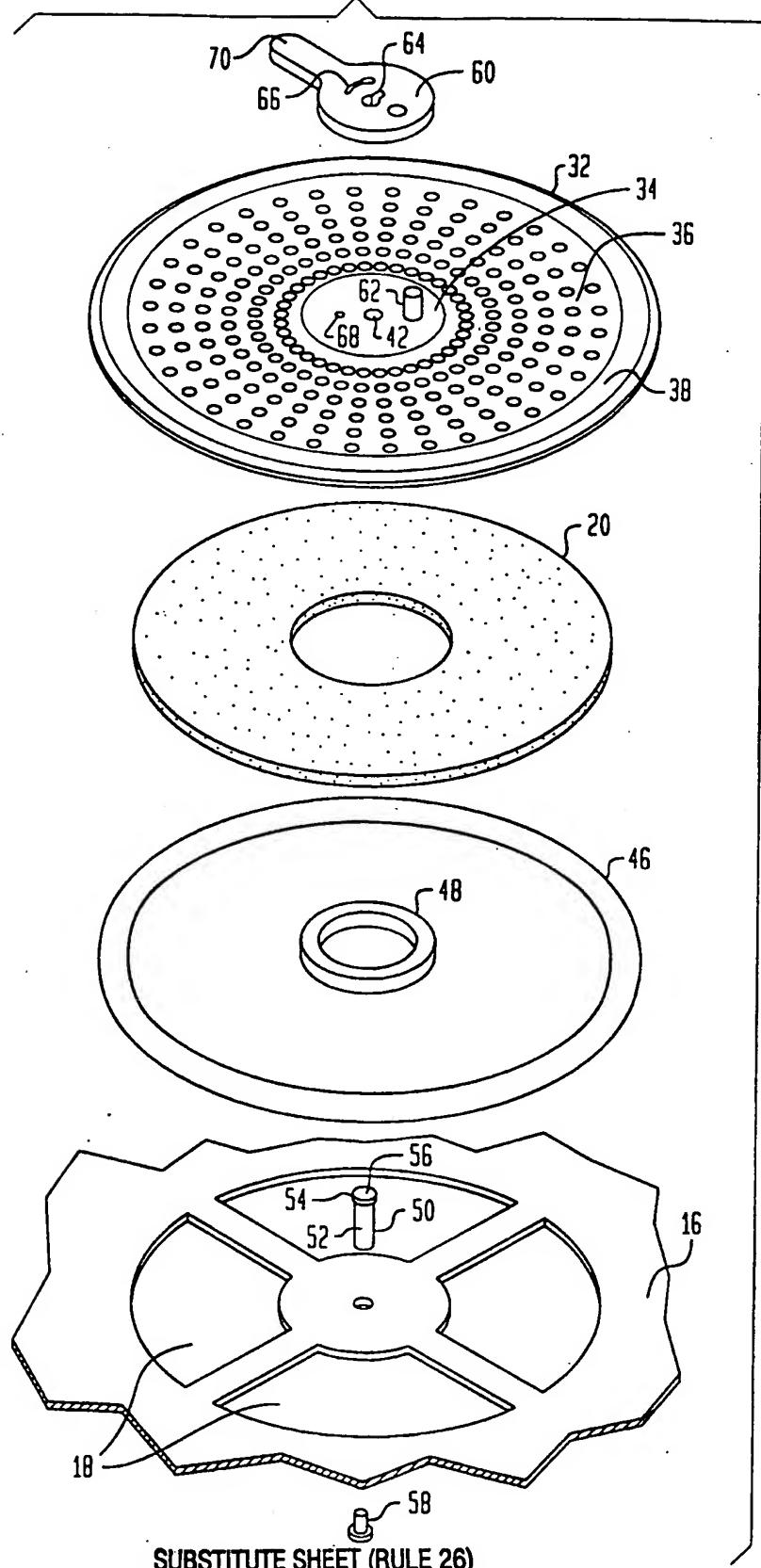
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FIG. 1C



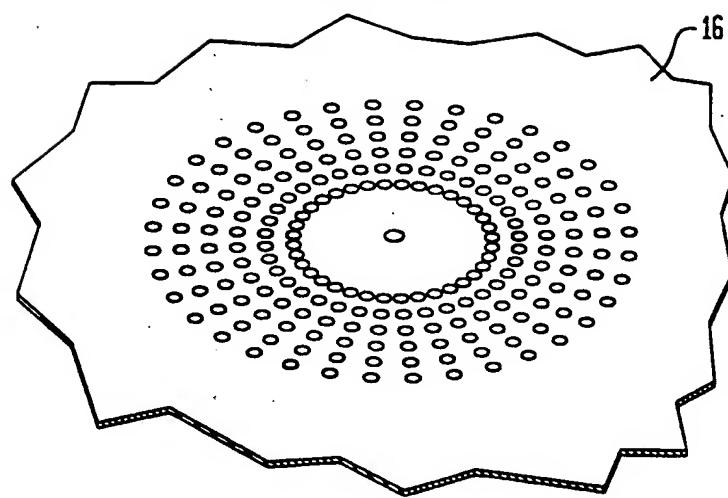
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FIG. 2A



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FIG. 2B



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FIG. 3A

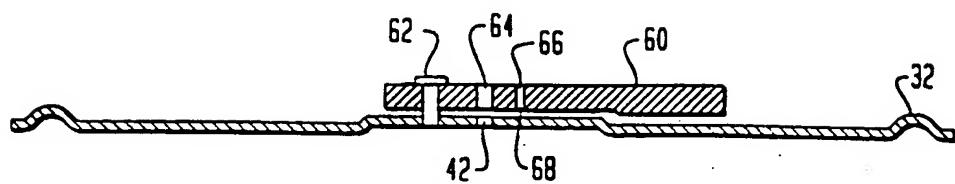
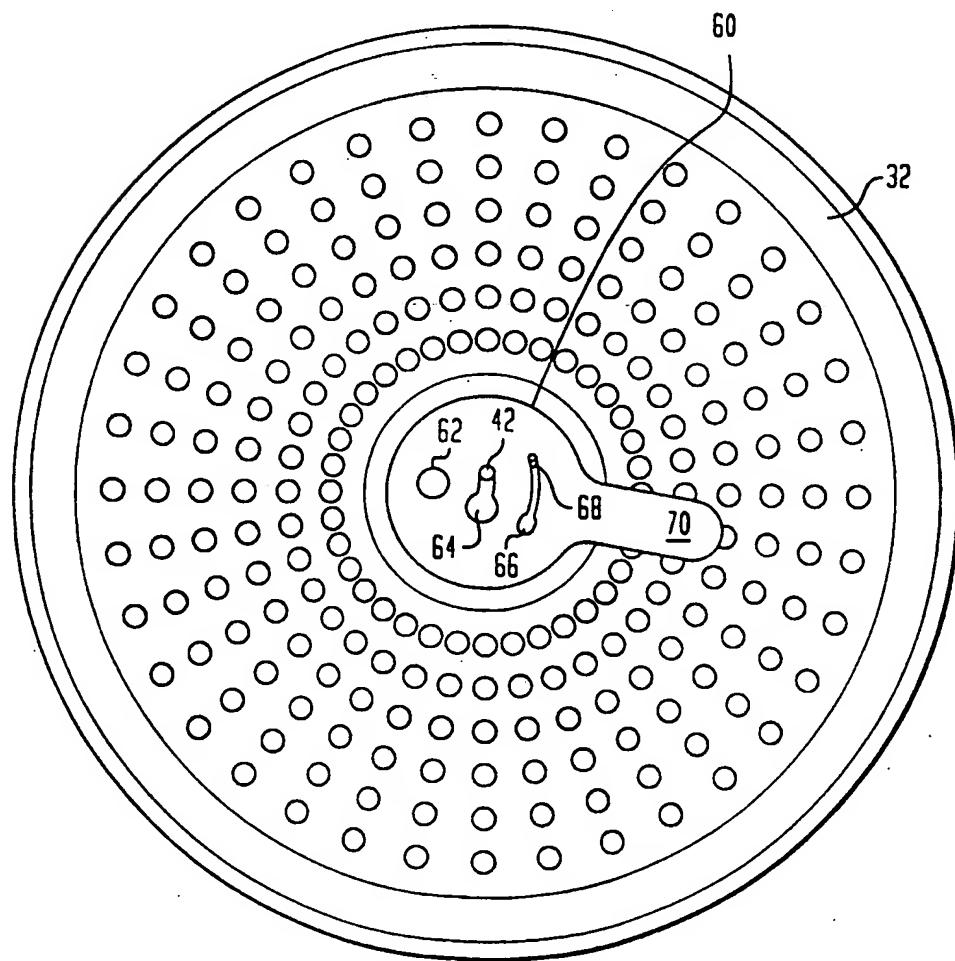
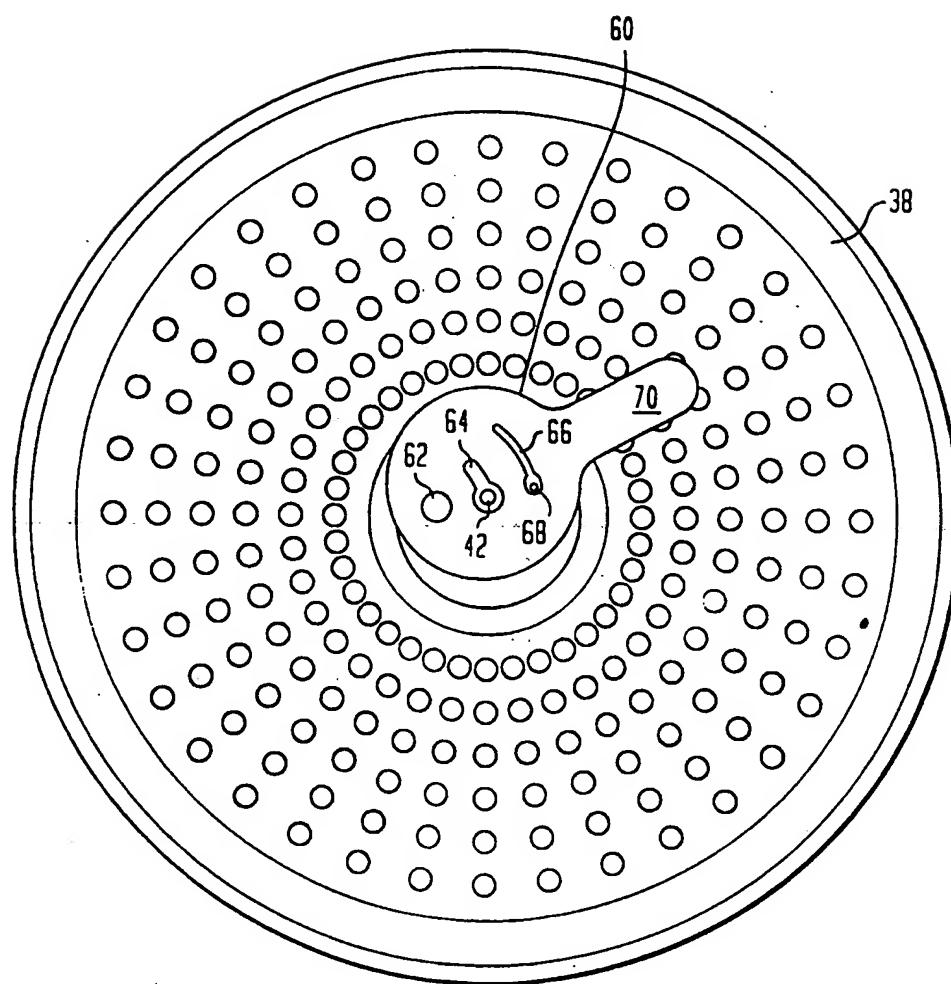


FIG. 3B



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FIG. 3C



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FIG. 4A

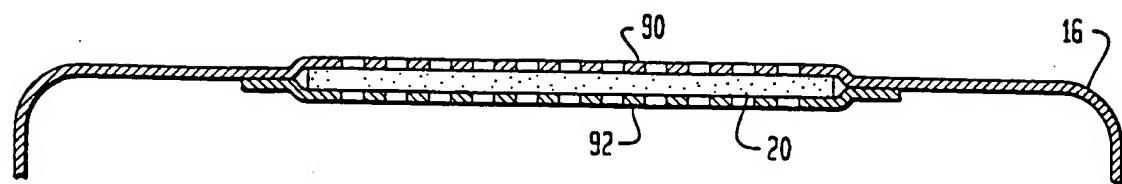
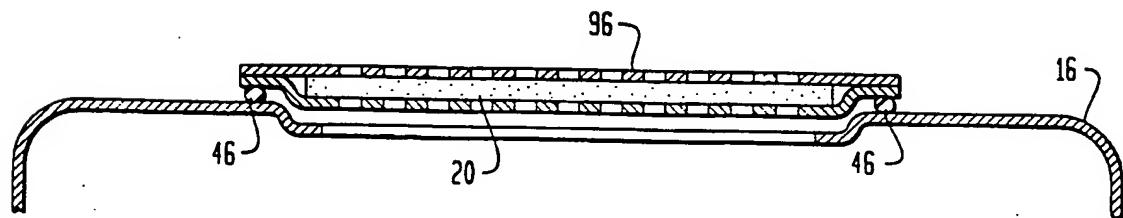
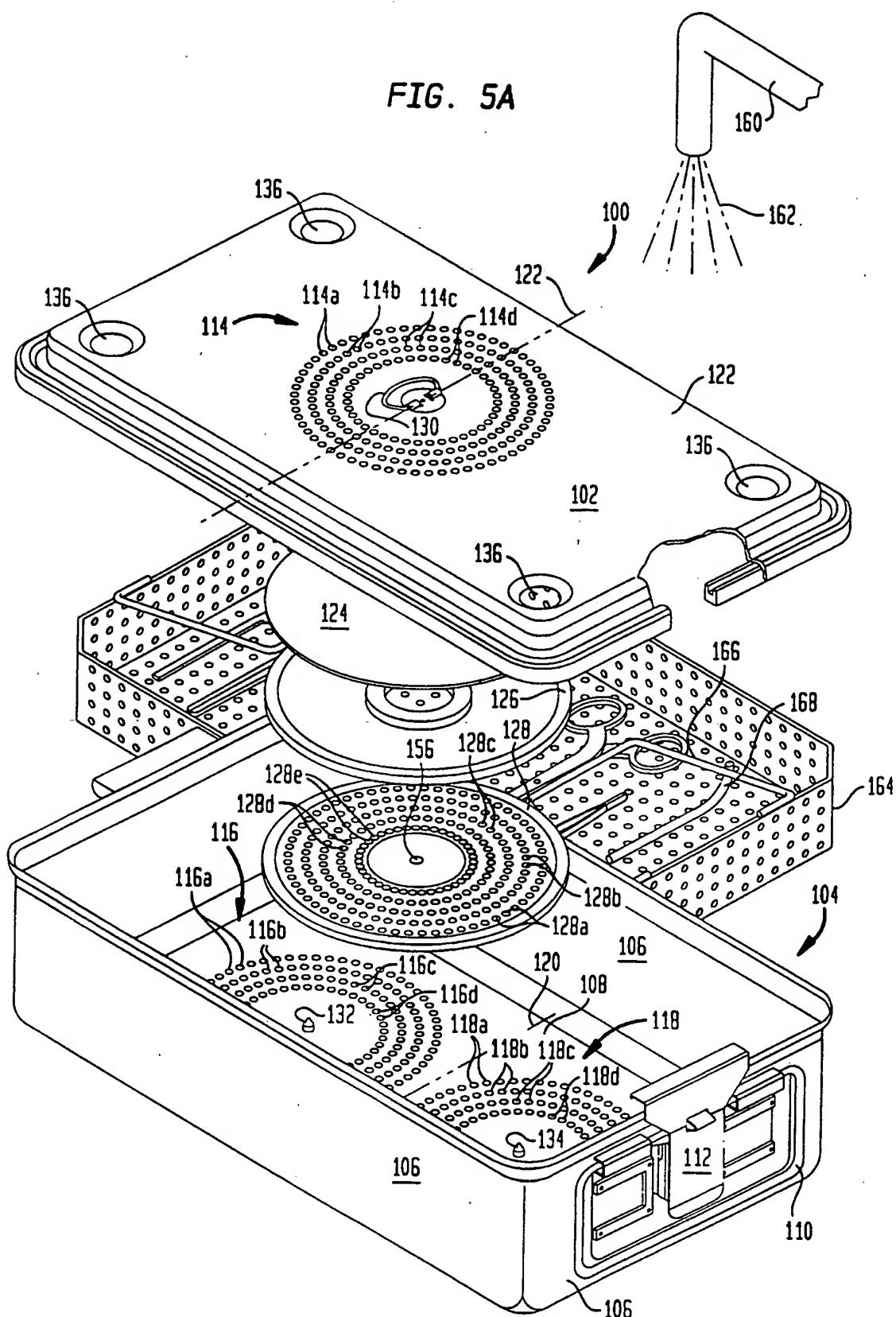


FIG. 4B



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FIG. 5A



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FIG. 5B

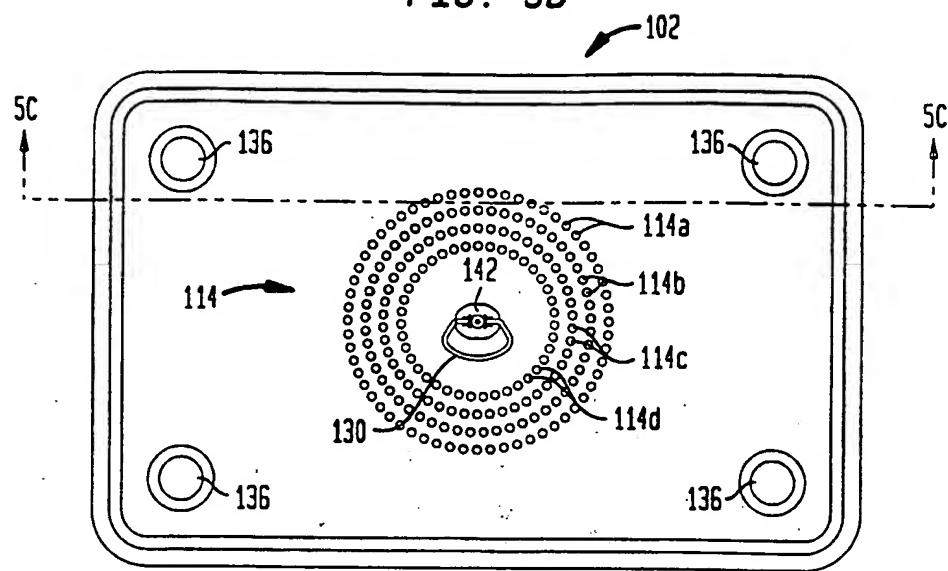


FIG. 5C

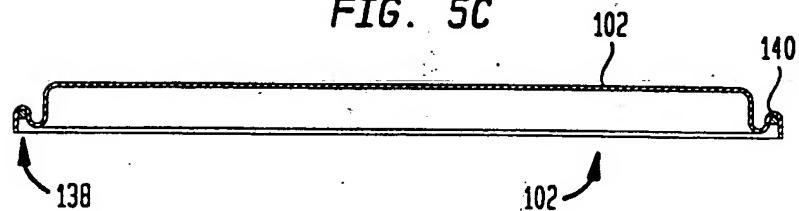
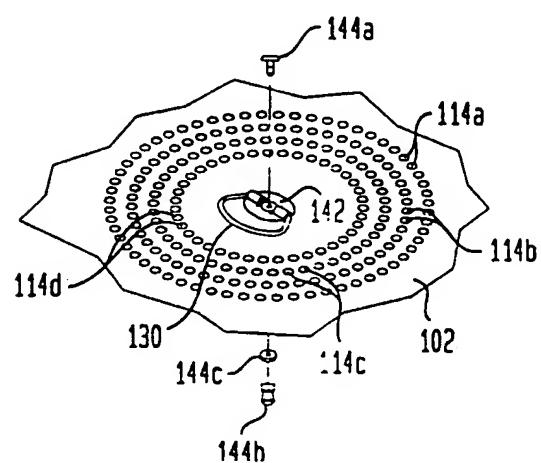


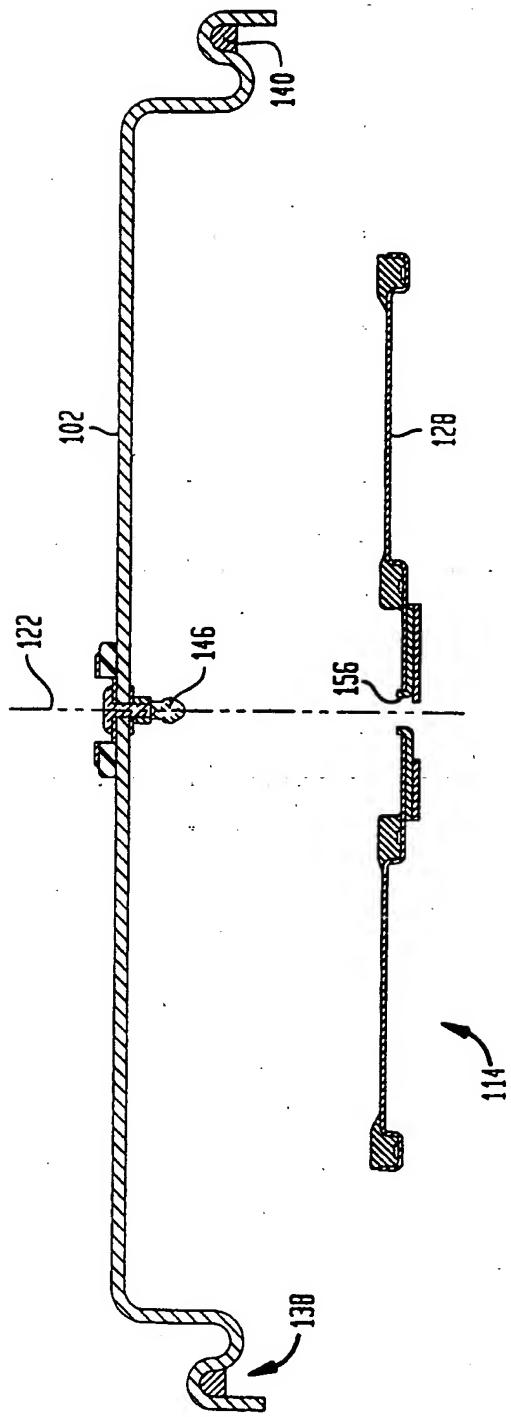
FIG. 5D



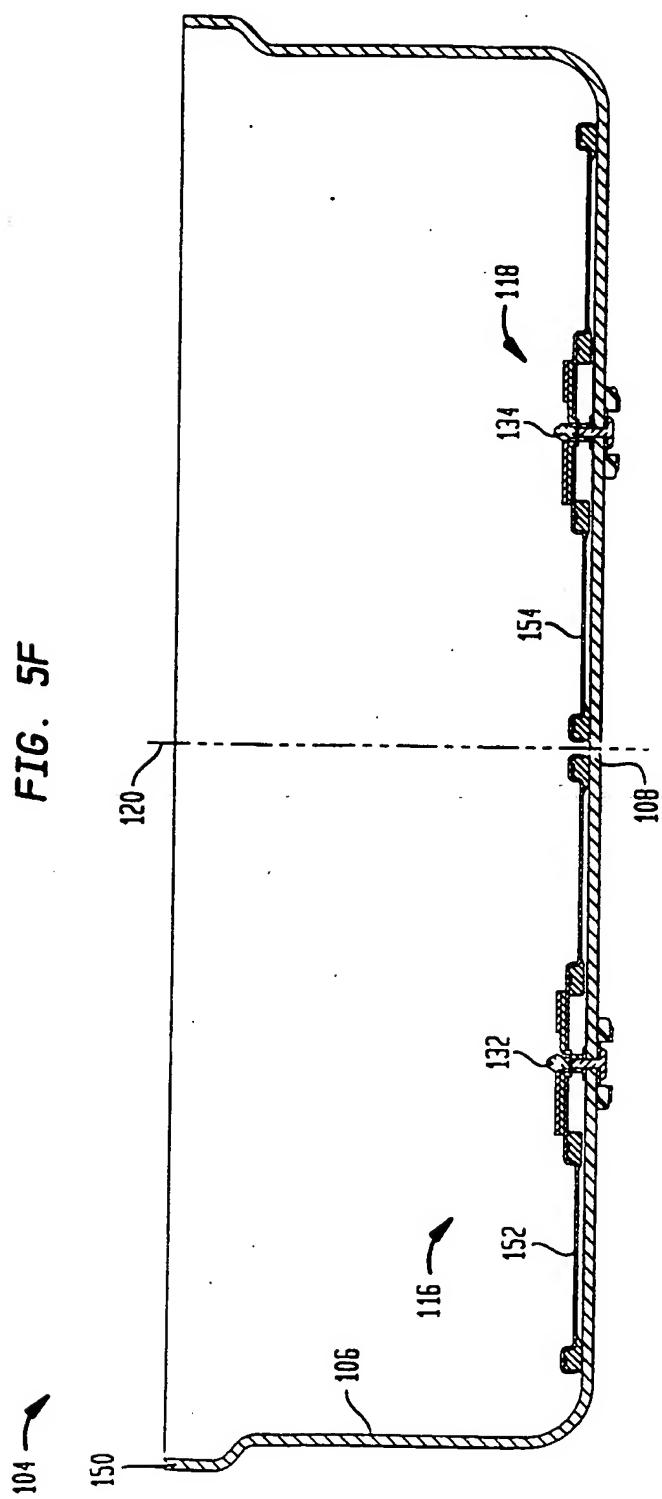
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FIG. 5E

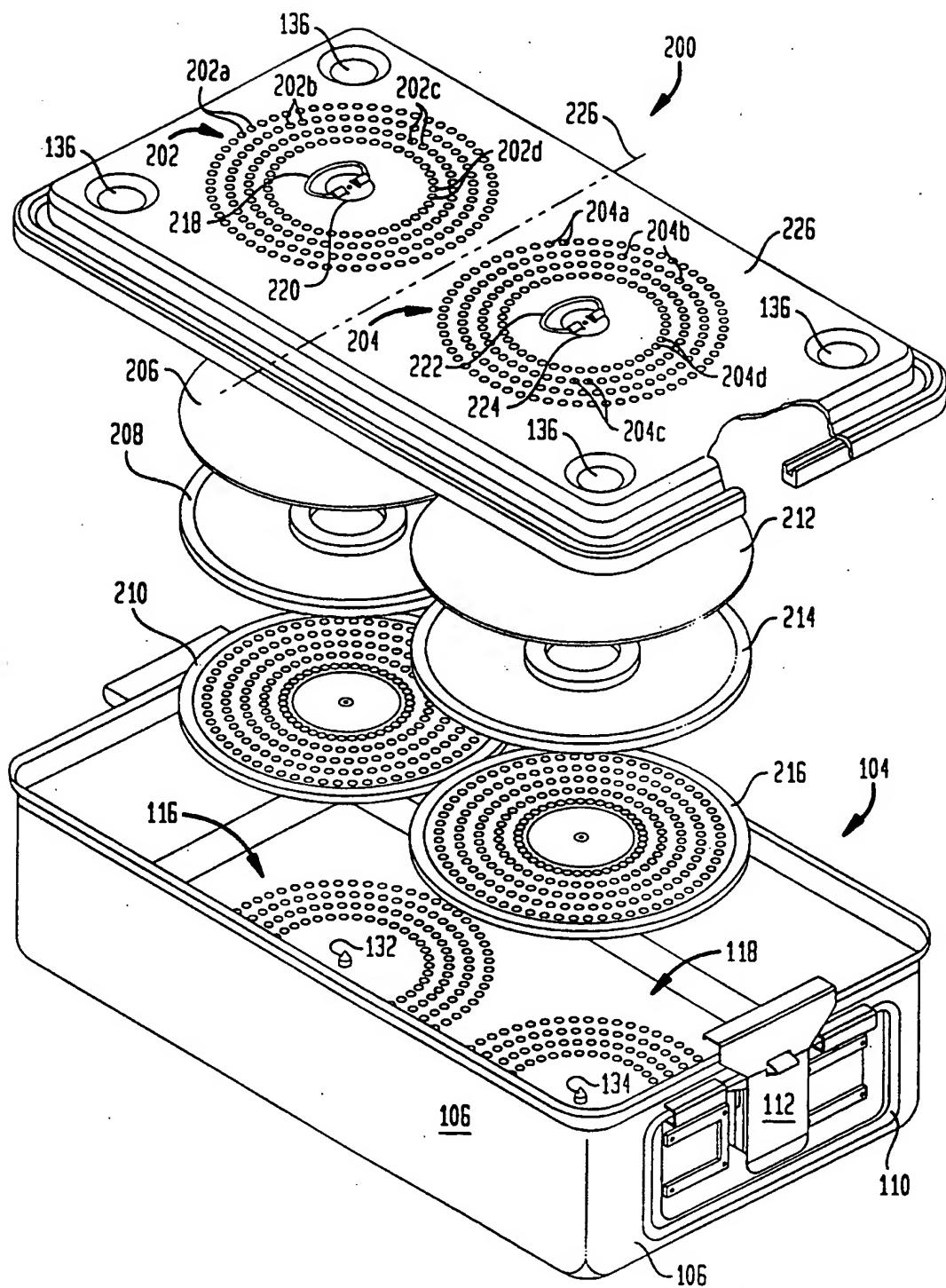


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FIG. 6A



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FIG. 6B

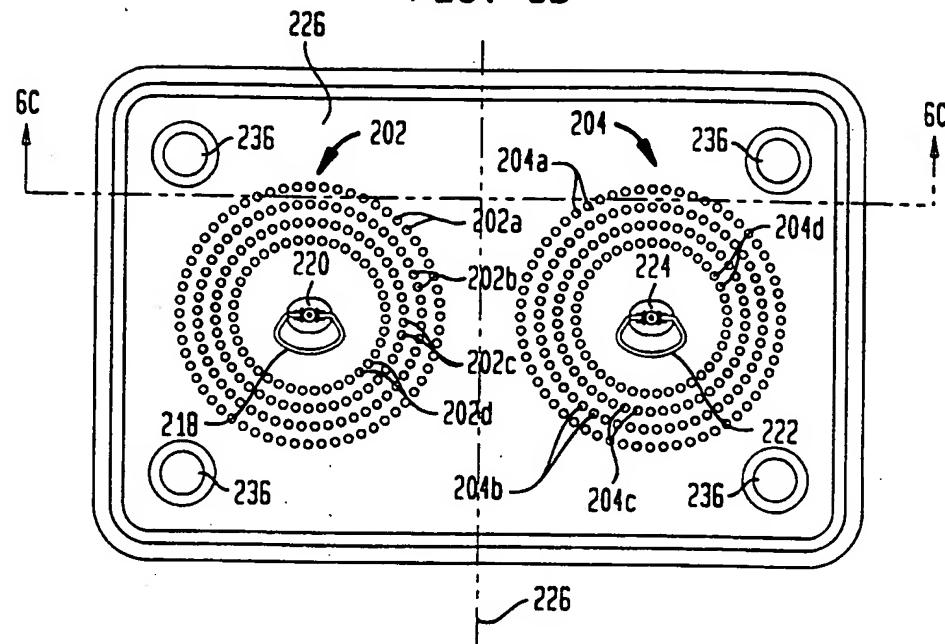


FIG. 6C

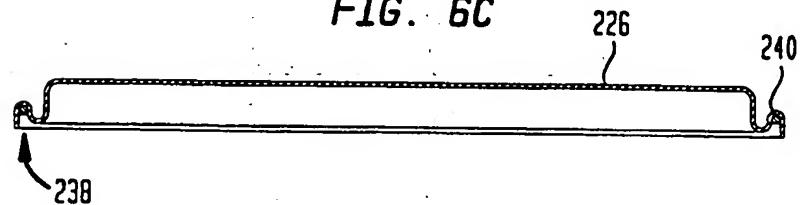
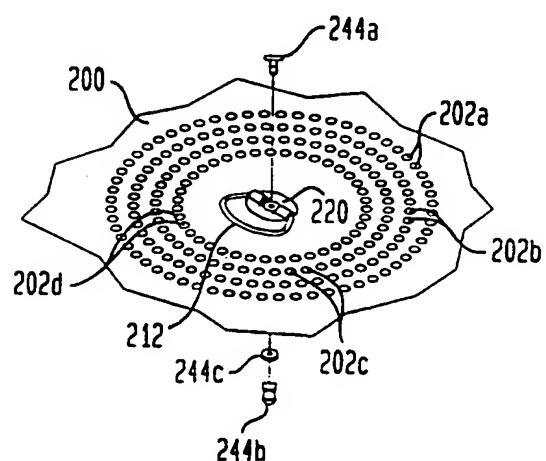


FIG. 6D



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/17671

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61L 2/00, 2/14, 2/20

US CL :422/297, 300; 220/371

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/26, 27, 292, 297, 300; 220/371, 315, 324, 327, 254, 293, 297; 215/308

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,628,970 A (BASILE et al) 13 May 1997, whole document, especially figures.	1-19
Y	US 5,474,738 A (NICHOLS et al) 12 December 1995, whole document, especially figures.	1-19

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

21 DECEMBER 1998

Date of mailing of the international search report

25 JAN 1999

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